General

Guideline Title

IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes.

Bibliographic Source(s)

Bus SA, Armstrong DG, van Deursen RW, Lewis JE, Caravaggi CF, Cavanagh PR, International Working Group on the Diabetic Foot. IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):25-36. [81 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the International Working Group on the Diabetic Foot (IWGDF): For the 2015 IWGDF Guidance documents, the IWGDF invited five working groups of international experts to produce guidance on the prevention and management of foot problems in diabetes. Major recommendations provided in the *IWDDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes* are presented below See also the NGC summaries of IWGDF guidance on the following related topics:

- Prevention of foot ulcers in at-risk patients with diabetes
- Diagnosis, prognosis, and management of peripheral artery disease in patients with foot ulcers in diabetes
- Diagnosis and management of foot infections in persons with diabetes
- Interventions to enhance healing of chronic ulcers of the foot in diabetes

Definitions for the quality of the evidence (High, Moderate, Low, Very Low) and strength of recommendations (Strong, Weak) are provided at the end of the "Major Recommendations" field.

Casting and Prefabricated Healing Devices

Are casting or prefabricated offloading effective techniques to heal plantar foot ulcers in patients with diabetes?

1. To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot–device interface. (Grading of Recommendations Assessment, Development and

Evaluation [GRADE] recommendation: Strong, Quality of evidence: High)

2. When a non-removable knee-high device is contraindicated or not tolerated by the patient, consider offloading with a removable knee-high walker with an appropriate foot–device interface to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only when the patient can be expected to be adherent to wearing the device. (Weak; Moderate)
3. When a knee-high device is contraindicated or cannot be tolerated by the patient, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only when the patient can be expected to be adherent to wearing the shoes. (Weak; Low)

Therapeutic Footwear

Is therapeutic footwear effective to prevent first or recurrent foot ulcers in patients with diabetes?

4. To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside. (Strong; Low)
5. Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis. (Strong; Low)
6. To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure-relieving effect during walking (i.e., 30% relief compared with plantar pressure in standard of care therapeutic footwear) and encourage the patient to wear this footwear. (Strong; Moderate)

Is therapeutic footwear effective to heal foot ulcers in patients with diabetes?

7. Do not prescribe, and instruct the patient with diabetes not to use, conventional or standard therapeutic shoes to heal a plantar foot ulcer. (Strong; Low)
8. Consider using shoe modifications, temporary footwear, toe spacers, or orthoses to offload and heal a non-plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. The specific modality depends on the type and location of the foot ulcer. (Weak; Low)

Surgical Offloading Interventions

Is surgical offloading effective to prevent first or recurrent foot ulcers in patients with diabetes?

9. Consider Achilles tendon lengthening (ATL), joint arthroplasty, single or pan metatarsal head resection, or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar forefoot ulcer. (Weak; Low)
10. Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes, and either a preulcerative sign or an ulcer on the distal toe. (Weak; Low)
11. To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, consider ATL, single or pan metatarsal head resection, or joint arthroplasty when conservative treatment fails. (Weak; Low)
12. To heal a distal toe ulcer without ischemia or uncontrolled infection in a patient with diabetes and hammertoes, consider digital flexor tenotomy when conservative treatment fails. (Weak; Low)

Other Offloading Interventions

Are any other offloading techniques effective to prevent or heal foot ulcers in patients with diabetes?

13. If other forms of biomechanical relief are not available, consider using felted foam in combination with appropriate footwear to offload and heal a neuropathic foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. (Weak; Low)

Definitions

Recommendations in this guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The authors assessed the quality of evidence on the risk of bias of included studies, effect sizes, and expert opinion, and rated the quality of evidence as 'high,' 'moderate' or 'low.' They assessed the strength of each recommendation as 'strong' or 'weak,' based on the quality of evidence, balance between benefits and harm, patient values and preferences, and costs (resource utilization). The rationale behind each recommendation is described in the original guideline document. See the GRADE Web site for more information.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Diabetic foot ulcers

Guideline Category

Prevention

Treatment

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Podiatry

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physical Therapists

Physician Assistants

Podiatrists

Guideline Objective(s)

To provide recommendations for prevention and healing of foot ulcers in patients with diabetes with footwear and offloading

Target Population

Persons with type 1 or 2 diabetes mellitus who are at risk for or have confirmed diabetic foot ulceration

Interventions and Practices Considered

1. Casting and prefabricated healing devices
    - Non-removable knee-high device

    - Removable knee-high walker
    - Forefoot offloading shoe, cast shoe, or custom-made temporary shoe
2. Therapeutic footwear
    - Instruction on how to protect feet and wear properly fitting footwear
    - Prescription of therapeutic shoes, custom-made insoles, or toe orthosis
    - Use of shoe modifications, temporary footwear, toe spacers, or orthoses
3. Surgical offloading
    - Achilles tendon lengthening (ATL), joint arthroplasty, single or pan metatarsal head resection, or osteotomy
    - Digital flexor tenotomy
4. Other offloading (felted foam in combination with appropriate footwear)

Note: Conventional or standard therapeutic shoes to heal a plantar foot ulcer was considered but not recommended.

Major Outcomes Considered

- Ulcer prevention
- Ulcer healing
- Reduction of mechanical pressure (i.e., offloading)
- Adverse effects of non-removable and removable knee-high offloading devices and all surgical offloading procedures

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The systematic review for this guideline (see the "Availability of Companion Documents" field) was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The systematic review was prospectively registered in the PROSPERO database for systematic reviews (CRD42014013647).

The population of interest for this systematic review was patients with diabetes mellitus type 1 or 2, and the clinical problem addressed was a foot ulcer. Primary outcome categories were as follows: ulcer prevention, ulcer healing, and the reduction of mechanical pressure, i.e., offloading. The interventions considered were four groups of techniques used throughout the world in clinical practice:

1. Casting: total contact cast (TCC); cast shoes.
2. Footwear: shoes; insoles; in-shoe orthoses; socks; insole plugs.
3. Surgical offloading: Achilles tendon lengthening (ATL); silicone injections/tissue augmentation; metatarsal head resection; osteotomy/arthroplasty/ostectomy/exostectomy; external fixation; flexor tendon transfer or tenotomy.
4. Other offloading techniques: bed rest; crutches/canes/wheelchairs; bracing (patella tendon bearing, ankle-foot orthoses); (non-)removable walkers; offloading dressings; felted foam/padding; callus debridement; walking exercise; and gait modification.

Each intervention group was defined *a priori*, and the literature was systematically searched for each group separately. Studies on healthy subjects or patients with other diseases than diabetes were not considered. Study designs that were included were systematic reviews and meta-analyses and original research conducted as randomized controlled trials (RCTs), non-randomized controlled trials (NRCTs), case–control studies, cohort studies, controlled before-and-after studies, interrupted time series, prospective and retrospective uncontrolled studies, cross-sectional studies, and case series. Case studies were excluded. Tracking of references in included articles was not performed.

Validation sets of approximately 20 publications were created for each intervention group, including key publications either known to the authors or from references in or to these known key publications. Using these sets, the systematic search was validated; that is, each publication in the set had to be identified in the literature search.

The search was performed on 29 July 2014 and covered references in all languages that were published since 1 May 2006. The following

databases were searched: PubMed, EMBASE via Ovid SP, Cumulative Index to Nursing & Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effect, Central Register of Controlled Trials, National Health Service Economic Evaluation Database, and Health Technology Assessment Database. The search strings for each database and are shown in online Appendices S1–S4 of the systematic review. In contrast to a previous systematic review, search terms for the search string included three rather than four categories: population, outcome, and intervention; study design was left out of the search string to increase sensitivity in the literature search.

For each intervention group, two members of the working group (i.e., observers) independently assessed records by title and abstract for eligibility for inclusion, based on four criteria: population, intervention, and outcome and now including study design as well. Cohen's kappa was calculated for agreement between observers. Any disagreement on inclusion of publications was discussed between observers until consensus was reached. Publications included in more than one intervention group were discussed among all group members and further analysed where most appropriate. Subsequently, full-article copies of included publications were obtained and assessed independently on the same four criteria for final eligibility for inclusion.

Number of Source Documents

The literature database search of records since 1 May 2006 identified a total of 666 records for casting, 1171 for footwear, 3300 for surgical offloading, and 3339 for other offloading interventions (see Figure 1 in the systematic review [see the "Availability of Companion Documents" field]). The systematic review authors identified two systematic reviews/meta-analyses, 20 randomized controlled trials (RCTs), four other controlled studies, and 54 non-controlled studies for review. This is in addition to the 12 RCTs, eight other controlled studies assessed in a previous systematic review, and three additional controlled studies from before 1 May 2006 that were newly identified. Twelve non-controlled studies from a previous systematic review were excluded because they were case studies or otherwise did not fit the scope.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Recommendations in the guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The authors assessed the quality of evidence on the risk of bias of included studies, effect sizes, and expert opinion, and rated the quality of evidence as 'high', 'moderate' or 'low'. See the GRADE Web site for more information.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The same two observers per intervention group independently assessed each controlled study for methodological quality (i.e., risk of bias) using scoring sheets developed by the Dutch Cochrane Centre. Equal weighting was applied to each validity item in the scoring sheet, and only those items rated as '+' contributed to the risk of bias score. The level of evidence of each article was based on study design and total risk of bias score using the Scottish Intercollegiate Grouping Network (SIGN) instrument: level 1 for randomized controlled trials (RCTs) and level 2 for non-randomized controlled trials (NRCTs), case–control, cohort, controlled before-and-after, or interrupted time series studies. Risk of bias was scored for each study as ++ (very low risk of bias), + (low risk of bias), or − (high risk of bias). Any disagreement between observers regarding risk of bias was resolved by discussion until a consensus was reached. Observers did not participate in the assessment and discussion of publications for which they were a co-author to prevent any conflict of interest. In these cases, another observer in the working group assessed the article.

Key data from each controlled study were extracted, summarized in an evidence table, and additionally described on a study-by-study narrative basis. One observer extracted the data; another checked the data. Separate risk-of-bias tables were developed. The evidence and risk-of-bias tables were discussed among all members of the working group. Included level 3 studies, i.e., prospective and retrospective uncontrolled studies, cross-sectional studies, and case series, were also assessed and summarized on a narrative basis.

The evidence table and narrative descriptions were combined with the existing evidence tables and descriptions from a previous systematic review covering the literature from before 1 May 2006. Controlled studies from before 1 May 2006 were reassessed for risk of bias if deemed necessary. Finally, the two observers per intervention group drew conclusions for each intervention based on the strength of the available evidence. These conclusions were discussed among all members of the working group, and final conclusions based on the available evidence were reached.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Following the systematic review, the experts in the working group formulated recommendations based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The GRADE system allows the experts to provide a rating for each recommendation based on both the strength with which it is recommended and the quality of the evidence underlying it. In this manner the link is made between scientific evidence and recommendations for daily clinical practice (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Recommendations in the guidance were formulated based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when writing a clinical guideline. The authors assessed the strength of each recommendation as 'strong' or 'weak', based on the quality of evidence, balance between benefits and harm, patient values and preferences, and costs (resource utilization). See the GRADE Web site for more information.

Cost Analysis

Costs and cost-effectiveness have received very little attention in studies on footwear and offloading, despite the fact that reimbursement through insured care is more and more dependent on proven cost-effectiveness.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Consensus

The members of the International Working Group on the Diabetic Foot (IWGDF) Editorial Board met in person on a number of occasions to thoroughly review the systematic reviews and the guidance documents, which were then revised by the working group based on this editorial review. When found satisfactory, the Editorial Board sent the guidance document to the IWGDF representatives for comments; the editorial board processed all comments received and made changes where needed in collaboration with the chair of the working group.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Foot ulcers are a major complication of diabetes mellitus, with high morbidity, mortality and costs. Yearly incidence is estimated to be around 2%, but this increases substantially when patients successfully heal from a foot ulcer, with reported recurrence rates between 30% and 40% in the first year. Prevention of these ulcers is of paramount importance to reduce the patient and economic burden.

Refer to the "Rationale" sections in the original guideline document for an assessment of balance of benefits and harms for each recommendation.

Potential Harms

- Possible adverse effects of non-removable knee-high devices include ankle joint immobilization, reduced activity level, potential risk of falls, knee or hip complaints due to asymmetry in walking from the unilaterally increased sole height, and pressure ulcers due to poor casting or fitting.
- Possible complications and side effects of surgical offloading techniques include infection, gait problems, acute Charcot neuro-osteoarthropathy (CN), and transfer ulcers. Risk of a heel ulcer after Achilles tendon lengthening (ATL) was 13% in 2 years in one study that also showed a 34% increase in heel peak pressure. In another study, risk for heel ulcers was 15% at a median 12 months follow-up that also showed that the highest risk for heel ulcers (47%) was in patients with heel anesthesia and significant dorsiflexion that was possible after ATL; these conditions therefore imply a contraindication. Other studies report no or only a small risk of heel ulceration from ATL. Risk of transfer ulcers after single metatarsal head resection was 41% in an average 13.1 months in one study, while two other studies did not report any transfer ulcers from this procedure at either 6 or 12 months follow-up. In non-selected patients with diabetic neuropathy undergoing foot and ankle surgery, post-operative surgical site infection developed in 9.5%. Based on these outcomes, it is not clear if the benefits outweigh the potential harm.

Refer to the "Rationale" sections in the original guideline document for an assessment of balance of benefits and harms for each recommendation.

Contraindications

Contraindications

- In one reported study, the risk for heel ulcers was 15% at a median 12 months follow-up that also showed that the highest risk for heel ulcers (47%) was in patients with heel anesthesia and significant dorsiflexion that was possible after Achilles tendon lengthening; these conditions therefore imply a contraindication.
- The traditional form of half-shoes, that only support the midfoot and heel, are contraindicated owing to risk of midfoot fracture.

Qualifying Statements

Qualifying Statements

Not stated

Implementation of the Guideline

Description of Implementation Strategy

Description of Implementation Strategy

Guidelines will be implemented via the training programs of the International Working Group on the Diabetic Foot (IWGDF) as well as with support of the translation of the guidelines in local languages.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Bus SA, Armstrong DG, van Deursen RW, Lewis JE, Caravaggi CF, Cavanagh PR, International Working Group on the Diabetic Foot. IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):25-36. [81 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Jan

Guideline Developer(s)

International Working Group on the Diabetic Foot - Nonprofit Organization

Source(s) of Funding

International Working Group on the Diabetic Foot

Guideline Committee

International Working Group on the Diabetic Foot

Composition of Group That Authored the Guideline

Authors: S. A. Bus, Department of Rehabilitation, Medicine, Academic Medical Center, University of Amsterdam, Amsterdam, The Netherlands; D. G. Armstrong, Southern Arizona Limb Salvage Alliance (SALSA), Department of Surgery, University of Arizona College of Medicine, Tucson, AZ, USA; R. W. van Deursen, School of Healthcare Sciences, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK; J. E. A. Lewis, Cardiff and Vale University Health Board and Cardiff School of Health Science, Cardiff Metropolitan University, Cardiff, UK; C. F. Caravaggi, Vita-Salute San Raffaele University, Milan, Italy, Diabetic Foot Clinic, Istituto Clinico Città Studi, Milan, Italy; P. R. Cavanagh, Department of Orthopaedics and Sports Medicine, University of Washington Medical Center, Seattle, WA, USA

Financial Disclosures/Conflicts of Interest

The International Working Group on the Diabetic Foot Guidance is developed by working groups of independent experts. These documents are written without any influence from commercial, political, academic or other interest groups.

Conflicts of Interest

PRC owns stocks in DIApedia and is an inventor on US patents 6,610,897, 6,720,470, and 7,206,718 that describe a load-relieving dressing and a method of insole manufacture for offloading diabetic feet. SB, RvD, DGA, JL, and CC: none declared.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Diabetes/Metabolism Research and Reviews Web site .

Availability of Companion Documents

The following are available:

- Bus SA, Armstrong DG, van Deursen RW, Lewis JE, Caravaggi CF, Cavanagh PR. Footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes: a systematic review. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):99-118. Available from the Diabetes/Metabolism Research and Reviews Web site .
- Bakker K, Apvelqvist J, Lipsky BA, Van Netten JJ, Schaper NC, International Working Group on the Diabetic Foot (IWGDF). The 2015 IWGDF guidance documents on prevention and management of foot problems in diabetes: development of an evidence-based global consensus. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):2-6. Available from the Diabetes/Metabolism Research and Reviews Web site .
- Schaper NC, Van Netten JJ, Apelqvist J, Lipsky BA, Bakker K, International Working Group on the Diabetic Foot (IWGDF). Prevention and management of foot problems in diabetes: a summary guidance for daily practice 2015, based on the IWGDF Guidance Documents. Diabetes Metab Res Rev. 2016 Jan;32(Suppl 1):7-15. Available from the Diabetes/Metabolism Research and Reviews Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 3, 2016. The information was verified by the guideline developer on December 11, 2016.

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.